

Title 10
DEPARTMENT OF HEALTH AND MENTAL
HYGIENE

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV)
INFECTION AND ACQUIRED IMMUNODEFICIENCY
SYNDROME (AIDS)

10.18.08 HIV [Counseling and] Testing Procedures

Authority: Health-General Article, §§2-104(b) and (i), 2-105(a) and (b), 18-102, 18-336, and 18-338.3, Annotated Code of Maryland

Notice of Proposed Action

[16-017-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .01—.05, repeal existing Regulations .06—.10, adopt new Regulations .06—.09, amend and recodify existing Regulation .11 to be Regulation .10, and recodify existing Regulation .12 to be Regulation .11 under **COMAR 10.18.08 HIV Testing Procedures**.

Statement of Purpose

The purpose of this action is to streamline and update processes related to HIV testing for health care providers and in nonclinical settings and ensure overall consistency across various related regulations. Health care providers are generally physicians, nurses, or the designee of a health care facility. Nonclinical settings are locations or settings where medical and/or treatment services are not provided. The consent process for HIV testing was streamlined for health care providers to allow consent to be collected in the same manner in which consent is collected for other medical procedures. Also, the amount and type of information which is to be delivered by health care providers to patients prior to testing has been reduced. No procedural changes were made in nonclinical settings.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. As a result of the changes to streamline pretest activities related to HIV testing, health care providers (including those in local health departments) may note a negligible positive economic impact. As clinical settings implement changes to the testing process, the time they spend with each patient to provide the required information prior to testing will be reduced. This may allow a health care provider to see more patients, which may increase revenue generated by the additional patients.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	(E+)	Indeterminable
	Benefit (+)	
	Cost (-)	Magnitude

D. On regulated industries or trade groups: (+) Indeterminable

E. On other industries or trade groups: NONE

F. Direct and indirect effects on public: NONE

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

C. Local governments have, within their local health departments, health care providers who will be impacted by the changes to the HIV testing process. As noted above, health care providers may see an increase in the number of patients they are able to see. The magnitude of the impact is not measurable as it will be dependent on the number of patients that can be seen, the number of health care providers who offer testing, and the volume of reimbursable services that are paid for by both public and private insurers.

D. Health care providers will be impacted by the changes to the HIV testing process. As noted above, health care providers may see an increase in the number of patients they are able to see. The magnitude of the impact is not measurable as it will be dependent on the number of patients that can be seen, the number of health care providers who offer testing, and the volume of reimbursable services that are paid for by both public and private insurers.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 8, 2016. A public hearing has not been scheduled.

.01 Scope.

A. Except as provided in [§§B—E] §§C—F of this regulation, this chapter governs pretest and post-test [counseling] information and requirements for informed consent when HIV testing is performed.

B. *In cases exempt from the requirements for consent throughout this chapter, as specified in §§C—F of this regulation, it is not necessary to obtain written informed consent for HIV testing on the form approved by the Secretary.*

[B.] C. If an HIV test is performed on an individual solely for the purpose of determining the suitability of that individual as a prospective donor of blood, semen, or tissue, the requirements for [counseling and written informed] information and consent are addressed in:

(1)—(2) (text unchanged)

[C.] D. If an HIV test is performed on an individual as a result of a court order issued under the provisions of the Criminal Procedure Article, §§11-107—11-117, Annotated Code of Maryland:

(1) The requirements for [counseling] *HIV testing* are addressed in COMAR 10.52.10; and

(2) (text unchanged)

[D.] E.—[F.] G. (text unchanged)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) *“Acquired immunodeficiency syndrome (AIDS)” means the medical condition caused by the human immunodeficiency virus.*

[(1)] (2) (text unchanged)

(3) *“Applicant” means a community based organization or other similar agency that seeks approval to become a designated human immunodeficiency virus testing site.*

(4) *“Appropriate entity” means the Department of Health and Mental Hygiene or the Baltimore City Health Department, which designate anonymous testing sites in the State.*

(5) *“Centers for Disease Control and Prevention (CDC)” means the federal Centers for Disease Control and Prevention of the federal Department of Health and Human Services.*

[(2)] (6)—[(3)] (7) (text unchanged)

[(4)] (8) *“Designated anonymous [test] testing site” means [an HIV counseling and] a human immunodeficiency virus testing site approved by the Department or the Baltimore City Health Department as a site where an individual may have an anonymous [HIV] human immunodeficiency virus test using a code rather than a name for identification.*

[(5)] (9) *“Health care facility” means a:*

(a)—(b) (text unchanged)

(c) Health maintenance organization as defined in Health-General Article, §19-701, Annotated Code of Maryland; [or]

(d) *The Department of Public Safety and Correctional Services; or*

(e) A program approved by the Department to provide [HIV counseling and] *human immunodeficiency virus* testing services, according to Regulations .03 and .04 of this chapter.

[(6)] “Health care practitioner” means a physician or other person authorized to order laboratory examinations under:

(a) Health Occupations Article, Annotated Code of Maryland; or

(b) COMAR 10.10.06.02.]

[(7)] (10) “Health care provider” means a[:

(a) Physician licensed under Health Occupations Article, Annotated Code of Maryland;

(b) Nurse licensed under Health Occupations Article, Annotated Code of Maryland; or

(c) Designee of a health care facility] *physician, nurse, or designee of a health care facility.*

[(8)] “HIV counseling” means communication of information to an individual that informs the individual about HIV infection, risks, tests for HIV, and means of preventing infection provided:

(a) Verbally;

(b) In writing;

(c) By video; or

(d) By any combination of §B(8)(a)—(c) of this regulation based on the testing history and information needs of the individual to be tested.

(9) “HIV infection” means an infection with HIV.]

[(10)] (11) “Human immunodeficiency virus (HIV)” means a virus that causes [acquired immune deficiency syndrome] *AIDS.*

[(11)] (12) “Indeterminate HIV test result” means that a test did not establish either the presence or absence of HIV infection as defined by the [Centers for Disease Control and Prevention] *CDC’s* laboratory criteria.

[(12)] (13) “Informed consent” means the voluntary permission by the individual to be tested for HIV, after the individual receives pretest [counseling] *information* as specified in [Regulation] *Regulations .06 and .07* of this chapter.

[(13)] (14) (text unchanged)

[(14)] (15) “Negative HIV test result” means the test result failed to document the presence of HIV as defined by the [Centers for Disease Control and Prevention] *CDC’s* laboratory criteria.

(16) *Nonclinical Settings.*

(a) “*Nonclinical settings*” means locations:

(i) *That are not health care settings;*

(ii) *Where medical or treatment services are not provided; and*

(iii) *Where selected diagnostic services and selected prevention services may be provided.*

(b) “*Nonclinical settings*” may include:

(i) *Community based organizations;*

(ii) *Outreach settings; or*

(iii) *Mobile vans.*

[(15)] (17) Partner.

(a) “Partner” means:

(i) [A sexual partner of the individual] *An individual with whom one has, or has had, oral, anal, or vaginal sexual contact; or*

(ii) An individual with whom [the individual] *one* has shared hypodermic needles or other similar drug paraphernalia.

(b) “Partner” includes [a current marital partner (spouse) or a previous marital partner (spouse) within the last 10 years] *any individual who is the marriage partner of an HIV-infected patient, or who has been the marriage partner of that patient at any time within the 10-year period before the diagnosis of HIV infection.*

[(16)] (18) “Positive HIV test result” means the test result has documented the presence of HIV as defined by the [Centers for Disease Control and Prevention] *CDC’s* laboratory criteria.

[(17)] (19) “Post-test [counseling] *information*” means [HIV counseling of an individual,] *notifying an individual about HIV test results and providing an individual with other relevant information* after an HIV test has been performed, [for the purpose of:

(a) Notifying the individual about the test results; and

(b) Imparting other relevant information] *as required by Regulations .08 and .09 of this chapter.*

[(18)] (20) “Pretest [counseling] *information*” means [HIV counseling of an individual] *providing an individual with information* before a specimen is [obtained for the purpose of testing] *tested* for the presence of HIV infection, *as required by Regulations .06 and .07 of this chapter.*

[(19)] (21)—[(23)] (25) (text unchanged)

.03 Requirements for Designated Anonymous [Counseling and] Testing Sites.

A. [A community based organization or other similar agency] *An applicant* shall seek approval from an appropriate entity to become a designated anonymous testing [site, as follows] *site from the*:

(1) [Community based organizations or other similar agencies providing services within Baltimore City shall seek approval from the] Baltimore City Health Department *for an applicant offering services in Baltimore City*; [and] *or*

(2) [Community based organizations or other similar agencies providing services outside of Baltimore City shall seek approval from the] Department *for an applicant offering services outside of Baltimore City*.

B. [A community based organization or other similar agency] *An applicant* that seeks approval to become a designated anonymous testing site shall *request an application from the appropriate entity and* submit [a written request] *a completed application in writing* to the appropriate [entity, which includes:

(1) A description of assessed need for HIV testing services at the proposed location that includes:

(a) The target population to be tested;

(b) The estimated number of individuals to be served; and

(c) An explanation of why the target population may not be adequately served by existing counseling and testing sites;

(2) A description of the on-site professional staff;

(3) The availability of on-site services and referrals offered to individuals;

(4) The method for providing referrals to individuals;

(5) The days and hours of operation;

(6) If applicable, the criteria for accepting individuals;

(7) Whether an appointment is required for HIV testing;

(8) Whether confidential HIV counseling and testing may be offered at the site;

(9) A description of funding sources that will pay for testing services, including fees for service;

(10) A statement of intent to comply with this chapter;

(11) A statement of intent to comply with COMAR 10.18.02 if confidential counseling and testing will be offered;

(12) Documentation of training by all HIV counselors. Training may be accomplished by:

(a) Completion of a HIV Counseling and Testing Skills Level I HIV counselor training program approved by the Department; or

(b) Completion of a similar skills training course that adheres to current Centers for Disease Control and Prevention guidelines;

(13) Implementation of an HIV counseling and testing protocol that:

(a) Ensures compliance with current Centers for Disease Control and Prevention HIV counseling, testing, and referral standards and guidelines;

(b) Includes an explanation of the method for assignment of a patient identifying code to ensure an individual's anonymity;

(c) Describes record keeping procedures to separate records of an anonymous test from a record with an individual's name;

(d) Describes procedures to maintain the security of an individual's information; and

(e) States that an HIV-positive individual will be offered assistance in notifying the individual's sexual and needle-sharing partners; and

(14) A statement of intent to report all HIV counseling and testing activity to the appropriate entity in a manner that is approved by that] entity.

C. The Department [and] *or* the Baltimore City Health Department shall:

(1) (text unchanged)

(2) Respond in writing to the written request [indicating]:

(a) [Approval to become a designated anonymous counseling and testing site;

(b) Disapproval] *Indicating approval or disapproval* to become a designated anonymous [counseling and] testing site; or

[(c)] (b) [A request] *Soliciting* for revision and resubmission of the *written* request.

.04 Requirements for Designated Confidential [Counseling and] Testing Sites.

A. [A community based organization or other similar agency] *An applicant* shall seek approval from an appropriate entity to become a designated confidential testing site[, as follows] *from the*:

(1) [Community based organizations or other similar agencies providing services within Baltimore City shall seek approval from the] Baltimore City Health Department *for an applicant offering services in Baltimore City*; [and] *or*

(2) [Community based organizations or other similar agencies providing services outside of Baltimore City shall seek approval from the] Department *for an applicant offering services outside of Baltimore City*.

B. [A community based organization or other similar agency] *An applicant* that seeks approval to become a designated confidential testing site shall *request an application from the appropriate entity and* submit [a written request] *a completed application in writing* to the appropriate [entity, which includes:

- (1) A description of assessed need for HIV testing services at the proposed location that includes:
 - (a) The target population to be tested;
 - (b) The estimated number of individuals to be served; and
 - (c) An explanation of why the target population may not be adequately served by existing counseling and testing sites;
- (2) A description of the on-site professional staff;
- (3) The availability of on-site services and referrals offered to individuals;
- (4) The method for providing referrals to individuals;
- (5) The days and hours of operation;
- (6) The criteria, if applicable, for accepting individuals;
- (7) Whether an appointment is required for HIV testing;
- (8) A description of funding sources that will pay for testing services, including fees for service;
- (9) A statement of intent to comply with this chapter;
- (10) A statement of intent to comply with COMAR 10.18.02;
- (11) Documentation of training by all HIV counselors which may be accomplished by completion of a:
 - (a) HIV Counseling and Testing Skills Level I HIV counselor training program approved by the Department;
- or
- (b) Similar skills training course that adheres to current Centers for Disease Control and Prevention guidelines;
- (12) Implementation of an HIV counseling and testing protocol that:
 - (a) Ensures compliance with current Centers for Disease Control and Prevention HIV counseling, testing, and referral standards and guidelines;
 - (b) Describes procedures to maintain the security of an individual's information; and
 - (c) States that an HIV-positive individual will be offered assistance in notifying the individual's sexual and needle-sharing partners; and
- (13) A statement of intent to report all HIV counseling and testing activity to the appropriate entity in a manner that is approved by that entity.
- C. The Department [and] or the Baltimore City Health Department shall:
 - (1) (text unchanged)
 - (2) Respond in writing to the written request [indicating]:
 - (a) [Approval to become a designated confidential counseling and testing site;
 - (b) Disapproval] *Indicating approval or disapproval* to become a designated confidential [counseling and] testing site; or
 - [(c)] (b) [A request] *Soliciting* for revision and resubmission of the *written* request.

.05 Denial and Reconsideration.

- A. An applicant under Regulation .03 or .04 of this chapter that has a written request denied by the appropriate entity may request reconsideration of the decision:
 - (1) (text unchanged)
 - (2) Within 30 *calendar* days of the date postmarked on the notice of denial.
- B. If an applicant requests a reconsideration according to §A of this regulation, the appropriate entity shall:
 - (1) Review the request for reconsideration and any supplemental documentation submitted by the applicant within 45 *calendar* days of the postmarked date on the letter requesting reconsideration; and
 - (2) (text unchanged)

.06 Consent and Pretest Requirements for HIV Testing by Health Care Providers.

- A. *General medical consent is:*
 - (1) *Required to be obtained only once during a patient's visit; and*
 - (2) *Sufficient to perform HIV testing.*
- B. *A health care provider who is obtaining consent for HIV testing shall:*
 - (1) *Obtain consent as a part of a patient's general consent for medical care in the same category as other screening and diagnostic tests; and*
 - (2) *Document all declinations of an HIV test in the medical record of the patient.*
- C. *The general informed consent for medical care may specify that an HIV test will be performed.*
- D. *Except as provided under Regulation .07 of this chapter, a health care provider may not be required to obtain consent for HIV testing on a separate consent form.*
- E. *Pretest information shall be provided to the patient to be tested for HIV before each specimen is tested.*
- F. *A health care provider providing pretest information shall:*
 - (1) *Provide HIV-specific information:*
 - (a) *Verbally;*
 - (b) *In writing;*
 - (c) *By video; or*
 - (d) *By any combination of §F(1)(a)–(c) of this regulation;*

- (2) Provide HIV information in a manner that protects the confidentiality of the patient being tested;
- (3) Using layman's terms, provide, at minimum, the following information to the patient being tested:
 - (a) That the patient is being tested for HIV;
 - (b) That the patient has the right to:
 - (i) Ask questions; or
 - (ii) Decline the test without penalty;
 - (c) An explanation of HIV infection;
 - (d) That a negative HIV test result means that:
 - (i) A patient is not infected with HIV or that the test was unable to detect the presence of HIV because a patient is in the early stage of infection and has not yet developed detectable evidence of HIV infection; and
 - (ii) If the patient has had any potential recent exposures, the patient should be retested within an appropriate time frame based on the type of testing used; and
 - (e) That a positive HIV test result means the patient:
 - (i) Is infected with HIV; and
 - (ii) Will be linked with medical treatment and other supportive services;
- (4) Include an opportunity for the individual being tested to:
 - (a) Ask questions about HIV infection and other topics described in this regulation and have those questions answered; and
 - (b) Decline HIV testing; and
- (5) Make necessary accommodation with respect to language or disability to ensure that the patient being tested understands the information presented.

.07 Consent and Pretest Requirements for HIV Testing in Nonclinical Settings.

A. For HIV tests administered in nonclinical settings, as permitted in Regulations .03 and .04 of this chapter, the individual administering the HIV test shall:

- (1) Utilize the HIV informed consent form approved by the Secretary to document the obtainment of informed consent;
- (2) Read and explain the HIV informed consent form, through an interpreter if necessary, to anyone who cannot read or understand the form's contents; and
- (3) Obtain voluntary written informed consent from the individual to be tested for HIV before an HIV test is performed on a specimen.

B. An individual tested at a designated anonymous nonclinical test site, as permitted in Regulation .03 of this chapter, may indicate consent by placing their assigned code on the signature line of the form approved by the Secretary to indicate written informed consent.

C. Pretest information shall be provided to the individual being tested before each specimen is tested.

D. An individual providing pretest information shall:

- (1) Provide HIV-specific information:
 - (a) Verbally;
 - (b) In writing;
 - (c) By video; or
 - (d) By any combination of §D(1)(a)—(c) of this regulation based on the testing history and information needs of the individual being tested;
- (2) Provide HIV information in a manner that protects the confidentiality of the individual being tested;
- (3) Using layman's terms, provide, at a minimum, the following information to the individual being tested:
 - (a) That the individual is being tested for HIV;
 - (b) That the individual has the right to:
 - (i) Ask questions; or
 - (ii) Decline the test without penalty;
 - (c) The primary modes of HIV transmission including:
 - (i) Sexual contact without the use of condoms, other barriers, or other biomedical interventions;
 - (ii) Injection drug use; and
 - (iii) Mother-to-child transmission.
 - (d) That a negative test result means that:
 - (i) An individual is not infected with HIV or that the test was unable to detect the presence of HIV because an individual is in the early stage of infection and has not yet developed detectable evidence of HIV infection; and
 - (ii) If the individual has had any potential recent exposures, that the individual should be retested within an appropriate time frame based on the type of testing used;
 - (e) That a positive test result means the individual:
 - (i) Is infected with HIV;
 - (ii) Will be linked with medical treatment and other supportive services; and
 - (iii) May need a confirmatory test if the preliminary positive was based on an HIV rapid test; and

(f) Inform the individual being tested at a designated anonymous HIV test site that an assigned code will be used instead of a name;

(4) Include an opportunity for the individual being tested to:

(a) Ask questions about HIV infection and other topics described in this regulation and have those questions answered; and

(b) Decline HIV testing; and

(5) Make necessary accommodation with respect to language or disability to ensure that the individual being tested understands the information presented.

.08 Post-Test Requirements for HIV Testing by Health Care Providers.

A. If a patient's test result is negative, the individual providing testing shall provide post-test information that includes:

(1) The test result was negative; and

(2) A review of the meaning of a negative result.

B. If a patient's test result is indeterminate, the individual providing testing shall provide post-test information to and in the presence of the patient tested that includes:

(1) The test result was indeterminate;

(2) A review of the meaning of an indeterminate test result;

(3) A recommendation that the patient return in a medically appropriate time frame for another test; and

(4) A recommendation that the patient take precautions as if the patient's test result had been positive until the patient is retested.

C. If a patient's test result is positive:

(1) The individual providing testing shall provide post-test information to and in the presence of the patient tested that includes:

(a) The test result was positive;

(b) A review of the meaning of a positive test result;

(c) Information regarding the patient's responsibility to notify all known sexual and needle-sharing partners of possible exposure or to request assistance from the local health department; and

(2) The health care provider shall:

(a) Ensure the patient is linked to an appropriate source of HIV medical care and supportive services;

(b) If necessary, provide the patient with information about mental health services for HIV-infected individuals; and

(c) Offer to assist the patient in notifying their partners that they may have been exposed to HIV and provide testing to their partners, or request that the local health officer conduct an investigation to assure partner notification has been completed.

.09 Post-Test Requirements for HIV Testing in Nonclinical Settings

A. If an individual's test result is negative, the individual providing testing shall provide post-test information that includes:

(1) The test result was negative;

(2) A review of the meaning of a negative result; and

(3) A recommendation about whether a repeat test is advisable based on potential recent exposures and the type of test technology used.

B. If an individual's test result is indeterminate, the individual providing testing shall provide post-test information to and in the presence of the individual tested that includes:

(1) The test result was indeterminate;

(2) A review of the meaning of an indeterminate test result;

(3) A recommendation that the individual return in a medically appropriate time frame for another test;

(4) A review of information regarding transmission of HIV and means of preventing transmission of HIV; and

(5) A recommendation that the individual take precautions as if the individual's HIV test result had been positive until the individual is retested.

C. If an individual's test result is positive:

(1) The individual providing testing shall provide post-test information to and in the presence of the individual tested that includes:

(a) The test result was positive;

(b) A review of the meaning of a positive test result;

(c) A review of information regarding transmission of HIV and means of preventing transmission of HIV;

(d) That the individual should have a medical evaluation by a physician or physician's designee who knows that the individual is HIV positive and should receive ongoing health care appropriate for an HIV seropositive individual; and

(e) If the individual is a female, a discussion of HIV transmission from mother to child in case of an unconfirmed pregnancy; and

(2) The health care provider shall:

(a) Ensure the individual is linked to an appropriate source of HIV medical care and supportive services, including evaluation and treatment for:

(i) Tuberculosis;

(ii) Hepatitis;

(iii) Pregnancy; and

(iv) Sexually transmitted infections;

(b) If necessary, provide the individual with information about mental health services for HIV-infected individuals; and

(c) Offer to assist the individual in notifying their partners that they may have been exposed to HIV and provide testing to their partners, or request that the local health officer conduct an investigation to assure partner notification has been completed.

[.11] .10 Health Care Providers, First Responders, and Public Safety Workers — HIV Exposure.

A.—B. (text unchanged)

C. A hospital's designated infection preventionist or employee health provider or its designee shall follow the requirements in Health-General Article, §18-338.3, Annotated Code of Maryland, if an exposure, as defined in Health-General Article, §18-338.3, Annotated Code of Maryland:

(1) (text unchanged)

(2) Is such that, in accordance with the [Centers for Disease Control and Prevention] *CDC's* recommendations, warrants recommending or offering chemoprophylaxis treatment for the health care provider, first responder, or public safety worker.

VAN T. MITCHELL
Secretary of Health and Mental Hygiene